Ser. No. 09/807,575
Amendment dated Jun. 19, 2006
Reply to Office action of Mar. 23, 2006

REMARKS/ARGUMENTS

Claim Objections

Claims 1, 3, and 4 were objected as including non-elected subject matter. The applicant agrees and corrected the objected claims accordingly by removing reference to syndecan-1.

General Remarks to Examiner's Anticipation Rejections

The examiner stated that, on the basis of Kleef et al (J Clin. Invest. 102(9):1662 et seq. 1998), the previously pending claims would be inherently anticipated as Kleef teaches that the human glypican-1 antibody would also recognize human glypican-1. Using that cross-reactivity, the examiner then relies on her assertion that the claimed subject matter would be identical in chemical structures and cited *In re Spada* 15 USPQ 2nd 1655, 1658 (Fed.Cir. 1990). To the extent that the preamble was ignored and under the assumption that the cross reactivity was significant the applicant agrees with the examiner's argument.

In response, the applicant amended the claims by adding further elements to the body of the claim, as well as by tying in the preamble to the claim elements to provide meaning to the claim. The so amended claims should give an even better understanding of the intent and scope of the claimed subject matter.

In this context, the applicant points out that it is well established that the determination of whether preamble recitations are structural limitations is resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990). Moreover, *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785 established that "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention"

Therefore, " ...if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.)

35 USC § 102 (b)

Claims 1-6 were rejected under 35 USC § 102(b) as being inherently anticipated by Karthikeyan et al. (Journal of Cell Science 107 32133-3222 (1994)). Similarly, **Claims 1-6** were rejected under 35 USC § 102(b) as being inherently anticipated by Ivins et al. (Developmental Biology 184 320-332 (1997)). The applicant disagrees, especially in view of the amendments made herein.

As amended herein, claim 1 expressly recites a "...diagnostic kit agent for detection of a human cancer cell that expresses glypican-1...", wherein "...an information [must be] associated with the binding molecule that binding of the binding molecule to a cell is indicative of a human cancer cell that expresses glypican-1..."

Likewise, amended claim 5 expressly requires that a "...therapeutic kit...[includes]...a therapeutic agent at a concentration effective to slow growth of human cancer cells identified to express glypican-1..." and "...an information associated with the molecule that binding of the binding molecule to the cancer cells slows growth of the cancer cells..."

These elements are neither inherently nor literally present in the cited references. All that Karthikeyan et al., and Ivins et al. teach are compositions and methods for detection of rat glypican in various non-cancerous neuronal tissues, and compositions and methods for detection of rat perlecan in various non-cancerous rat neuronal tissues, respectively. These references are entirely silent on an information that is associated with a glypican-1 binding composition as

previously claimed, let alone of an information as presently claimed in the context of the preamble. Therefore, and at least for these reasons, claims 1-6 should not be deemed anticipated by Karthikeyan et al. and Ivins et al.

35 U.S.C. § 102 (a)

Claims 1-6 were rejected under 35 USC § 102(b) as being inherently anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864 (1997)), Liu et al. (The Journal of Biological Chemistry 273(35) 22825-22832 (1998)), and by Litwack et al. (Developmental Dynamics 211 72-87 (1998)). The applicant once more disagrees, especially in view of the amendments made herein.

As above, amended claim 1 specifically requires a "...diagnostic kit agent for detection of a human cancer cell that expresses glypican-1...", wherein "...an information [must be] associated with the binding molecule that binding of the binding molecule to a cell is indicative of a human cancer cell that expresses glypican-1...", and amended claim 5 expressly requires that a "...therapeutic kit...[includes]...a therapeutic agent at a concentration effective to slow growth of human cancer cells identified to express glypican-1..." and "...an information associated with the molecule that binding of the binding molecule to the cancer cells slows growth of the cancer cells." "

In contrast, Liang et al. teach compositions and methods for detection of glypican and/or heparan in various non-cancerous rat neuronal tissues, Liu teaches compositions and methods for Western and dot blot detection of glypican-1, and Litwack et al. teach compositions and methods for detection of glypican-1 in various non-cancerous rat tissues (neuronal and others). Therefore amended claims 1-6 should not be deemed anticipated by Liang, Liu, and/or Litwack as all of those references fail to teach compositions and use of the glypican antibodies as previously claimed.

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REQUEST FOR ALLOWANCE

Claims 1-6 are pending in this application. The applicant requests allowance of all pending claims.

Respectfully submitted,

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